

REMARKS

Claims 1-21 are pending in this application. Claims 18-21 have been newly added.

Claims 18-21 have been added for the sole reason of advancing prosecution. Applicants, by adding new claims herein, make no admission as to the validity of any rejection made by the Examiner against any claims.

Newly added claims 18-21 are directed to the "formulation according to claim 1, wherein the glycolide is present in amount from" 30-90%, 30-80%, 50-90%, and 50-80% by weight, respectively. Support for newly added claims 18-21 can be found, for example, at page 5, lines 4-6 of the specification as originally filed.

No new matter has been added.

In view of the following, further and favorable consideration is respectfully requested.

- I. At page 2 of the Official Action, claims 1-3, 5-8, 11 and 17 have been rejected under 35 USC § 102(b) as being anticipated by WO 2000/059556 (Besemer et al.).***

The Examiner asserts that Besemer et al. anticipates each element of claims 1-3, 5-8 and 17.

In view of the remarks herein, this rejection is respectfully traversed.

The test for anticipation is whether each and every element as set forth is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP § 2131. The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131.

The elements must also be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

As discussed, present claim 1 is directed to a formulation effective in reducing the pH in a menstruating vagina or in a tampon inserted therein to below pH 5.5 comprising: (a) 3-100% by weight of glycolide; (b) optionally, 97-15% by weight of a solid organic acid; and (c) optionally, 5-30% of a wetting agent. Claims 2-3 and 5-8 depend, directly or indirectly, from claim 1.

Claim 11 is directed to a formulation effective in reducing the pH in a menstruating vagina or in a tampon inserted therein to below pH 5.5 comprising: (a) 3-100% by weight of glycolide; (b) optionally, 3-97% by weight of lactide; (c) optionally, 97-15% by weight of a solid organic acid; and (d) optionally, 5-30% of a wetting agent.

Claim 17 is directed to a formulation effective in reducing the pH in a menstruating vagina or in a tampon inserted therein to below pH 5.5, consisting of: (a) 3-100% by weight of glycolide; (b) optionally, 3-97% by weight of lactide; (c) optionally, 97-15% by weight of a solid organic acid; and (d) optionally, 5-30% of a wetting agent.

In contrast to the presently claimed subject matter, Besemer et al. is directed to a superabsorbent material for controlling odor and bacterial growth which comprises a non-acidic, alkali-neutralizing compound selected from acid anhydrides, lactides, lactones and hydrolysable esters. See, for example, paragraphs 1-2 and 8 of Besemer et al. The superabsorbent material described in Besemer et al. is intended for use in hygiene products such as diapers and sanitary napkins. See, for example, Examples 1-3 of Besemer et al. as well as the Abstract. Examples of the superabsorbent material according to Besemer et al. are crosslinked polyacrylates and polysaccharides grafted with

polyacrylates. See *Id.* at paragraph 2. As described in Besemer et al., odor control is achieved by combining an alkali-neutralizing compound with the superabsorbent material. One example of an alkali-neutralizing compound described in Besemer et al. is glycolide. See *Id.* at paragraphs 4, 5 and 14, as well as claim 3.

However, unlike the presently claimed subject matter, Besemer et al. do not teach a “formulation ***effective in reducing the pH in a menstruating vagina or in a tampon inserted therein*** to below pH 5.5” either comprising or consisting of glycolide, as recited by each of the pending independent claims. In this regard, Applicants submit that Besemer et al. do not mention a tampon, a vagina or even any absorbent material for insertion into the human body. In fact, Applicants note that the only mention of glycolide in Besemer et al. is with reference to the use of glycolide on a diaper which already contains lipolase T 100 to reduce the pH of the diaper. See Besemer et al. at page 4, Example 3 and Table 4. Applicants respectfully submit that a diaper is not analogous to a tampon, especially a diaper comprising a superabsorbent material including lipolase T 100 and glycolide for improving odor control. In addition, Applicants submit that Besemer et al. only describes hygienic absorbent products which are used externally. Accordingly, Besemer does not teach a formulation, as recited, effective in reducing pH ***in*** a menstruating vagina or ***in*** a tampon ***inserted therein***. Additionally, Applicants note that, as known by those skilled in the art, the use of superabsorbent materials in tampons is prohibited since they may promote toxic shock syndrome. Accordingly, a skilled artisan would not contemplate using the diaper or sanitary napkin described in Besemer et al. as a tampon.

In view of the foregoing, it is submitted that Besemer et al. does not teach, either

expressly or inherently, each and every element of the presently claimed subject matter, as required for anticipation under 35 USC § 102 (b). Accordingly, the Examiner is respectfully requested to withdraw this rejection.

II. At page 2 of the Official Action, claims 1-17, have been rejected under 35 USC §103(a) as being unpatentable over Besemer et al. in view of Kluger et al. (of record) and in further view of Sinclair et al. (US Patent No. 5,444,113).

The Examiner asserts that it would have been obvious to the skilled artisan to use a combination of the teachings of Kluger et al. along with the teachings of Zhao et al. to arrive at the claimed formulation because Kluger et al. describes a formulation for reducing the pH in a menstruating vagina by inserting a tampon made from solid organic acid polymer and solid organic acid and a wetting agent, and Zhao et al. teaches a flushable tampon applicator made from biodegradable components such as lactide copolymers and glycolide polymers.

In view of the remarks herein, this rejection is respectfully traversed.

To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court held in *KSR International Co. v. Teleflex Inc. et al.*, Slip Opinion No. 04–1350, 550 U. S. ____ (April 30, 2007), “a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the

relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” (*KSR, supra*, slip opinion at 13-15.) Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

Recently, the Federal Circuit in *Takeda Chemical Industries v. Alphapharm*, No. 06-1329, slip op. (Fed. Cir. June 28, 2007), has **applied the TSM test after KSR**. The Appellant in this declaratory judgment action argued that the claimed chemical compound was an obvious modification of a previously known compound—the modification requiring the substitution of a homolog in a different ring position. (*Id.* at 5.) The Federal Circuit rejected this, holding that “in cases involving new chemical compounds, it remains necessary to identify some reasons that would have led a chemist to modify a known compound in a particular manner to establish *prima facie* obviousness of a new claimed compound.” (*Id.* at 10.) Notably, the Court also rejected the Appellant’s “obvious to try” argument, as the Appellant failed to demonstrate that one of ordinary skill would have chosen the prior art compound to modify from the millions of possibilities. (*Id.* at 15.)

It is submitted that a *prima facie* case of obviousness has not been established because there is no motivation to combine Besemer et al., Kluger et al. and Sinclair et al., and because, whether taken alone or in combination, Besemer et al., Kluger et al. and

Sinclair et al. do not teach or suggest all the limitations of the present claims as required by *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

From the outset, Applicants note that there is no motivation to combine Besemer et al., Kluger et al. and Sinclair et al. because each of the cited references are directed to entirely different subject matter. In this regard, none of the cited references describe subject matter useful for the same purpose. Specifically, Applicants note that Besemer is directed to improving odor control of urine in diapers and sanitary napkins. In contrast, Kluger describes reducing the pH in a menstruating vagina or in a tampon inserted therein. On the other hand Sinclair et al. describes the production of commercial products which are easily degraded. Applicants respectfully submit that a person of ordinary skill in the art would not be motivated to combine the teachings gleaned from any of: a reference describing diapers; a reference describing the reduction of the pH of a vagina or tampon inserted in a vagina; and a reference directed to the production of commercial products. Accordingly, Applicants submit that there is no motivation to combine the cited reference.

Assuming *arguendo* that the combination of references is proper, none of Besemen et al., Kluger et al. nor Sinclair et al. teach or suggest all the limitations of the claims as required by *In re Wilson*. Specifically, whether taken alone or in combination, none of Besemen et al., Kluger et al. nor Sinclair et al. teach or suggest a “formulation **effective in reducing the pH in a menstruating vagina or in a tampon inserted therein** to below pH 5.5” either comprising or consisting of glycolide, as recited by each of the pending independent claims.

As discussed, present claim 1 is directed to a formulation effective in reducing the pH in a menstruating vagina or in a tampon inserted therein to below pH 5.5 comprising:

(a) 3-100% by weight of glycolide; (b) optionally, 97-15% by weight of a solid organic acid; and (c) optionally, 5-30% of a wetting agent. Claims 2-10 and 12-15 depend, directly or indirectly, from claim 1.

Claim 11 is directed to a formulation effective in reducing the pH in a menstruating vagina or in a tampon inserted therein to below pH 5.5 comprising: (a) 3-100% by weight of glycolide; (b) optionally, 3-97% by weight of lactide; (c) optionally, 97-15% by weight of a solid organic acid; and (d) optionally, 5-30% of a wetting agent. Claim 16 depends from claim 11.

Claim 17 is directed to a formulation effective in reducing the pH in a menstruating vagina or in a tampon inserted therein to below pH 5.5, consisting of: (a) 3-100% by weight of glycolide; (b) optionally, 3-97% by weight of lactide; (c) optionally, 97-15% by weight of a solid organic acid; and (d) optionally, 5-30% of a wetting agent.

Applicants would like to politely emphasize that the present subject matter is directed to a formulation comprising glycolide, and not a solid product made up of glycolide. Additionally, the presently claimed formulation reduces the pH in a menstruating vagina or in a tampon inserted therein. Further, the presently claimed formulation contains glycolide and not a polymer thereof.

Besemer et al. is discussed above with regard to the rejection under 35 USC § 102(b). As discussed, Besemer et al. do not teach or suggest a “formulation **effective in reducing the pH in a menstruating vagina or in a tampon inserted therein** to below pH 5.5” either comprising or consisting of glycolide, as recited by each of the pending independent claims.

Kluger et al. do not remedy the deficiencies of Besemer et al. Kluger et al. describes a formulation effective for reducing the pH in a menstruating vagina or in a tampon inserted therein to below pH 5.5, comprising in part, 3-80% by weight of a solid

organic acid polymer. Specifically, Kluger et al. describes a formulation effective in reducing the pH in a menstruating vagina or in a tampon inserted therein to below pH 5.5, comprising (a) 3-80% by weight of a solid organic acid polymer; (b) 92-15% by weight of a solid organic acid, and (c) 5-30% of a wetting agent. Kluger et al. describes various examples of a solid organic acid polymer. However, unlike the presently claimed subject matter, Kluger et al. **do not** teach or suggest the use of **glycolide**. In fact, the term “glycolide” **does not appear at all** in Kluger et al. One of ordinary skill in the art would have no reason to use glycolide for the solid organic acid polymer based on the disclosure of Kluger et al. Accordingly, like Besemer et al., Kluger et al. do not teach or suggest a “formulation **effective in reducing the pH in a menstruating vagina or in a tampon inserted therein** to below pH 5.5” either comprising or consisting of glycolide. Therefore, whether alone or in combination, none of the cited references teach or suggest the presently claimed subject matter.

Sinclair et al. do not remedy the deficiencies of Besemer et al. and Kluger et al. Sinclair et al. is directed to products made of degradable materials which include a hydrolytically degradable polymer. See Sinclair et al. at the Abstract. However, like Besemer et al. and Kluger, Sinclair et al. also do not teach or suggest a “formulation **effective in reducing the pH in a menstruating vagina or in a tampon inserted therein** to below pH 5.5” either comprising or consisting of glycolide, as presently claimed. Sinclair et al. describes degradable materials are useful for the production of commercial products which are easily degraded, thus contributing to improving the environment. See Sinclair et al. at col. 4, lines 35-49). The disclosed polymer is characterized as comprising *repeating* monomer or comonomer units derived from, for example, glycolide. See Sinclair et al. at

col. 7, lines 33-50. However, as indicated above, the presently claimed subject matter recites ***the monomer glycolide, and not polymers of glycolide***. Therefore, whether taken alone or in combination, none of the cited references teach or suggest a "formulation effective in reducing the pH in a menstruating vagina or in a tampon inserted therein to below pH 5.5" either comprising or consisting of glycolide, as presently claimed.

In addition, with specific regard to Kluger et al., Applicants submit that as described in the examples of the present specification, the use of glycolide imparts significant advantages to the presently claimed formulation. In this regard, Applicants note that the solid organic acid and wetting agent are required ingredients in the formulation described in Klugar et al. In contradistinction, according to present claim 1, the organic acid and the wetting agent are optional components that, if present, may be used in the alternative. Applicants respectfully submit that this is due to the unexpected, superior pH reducing properties of glycolide. See, for example, Figures 4 and 6, as well as the page 7, line 24 to page 8, line 19 of the present specification.

In view of the foregoing, it is submitted nothing in Beseman et al., Kluger et al. and Sinclair et al., taken alone or in combination, renders the presently claimed subject matter obvious within the meaning of 35 U.S.C. § 103(a). Therefore, Applicants respectfully submit a *prima facie* case of obviousness has not been established. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

III. Claims 18-21

Applicants respectfully submit that newly added claims 18-21 are also novel and non-obvious. In this regard, Applicants submit that claims 18-21 are novel and non-obvious for at least the reason that the new claims depend from claim 1, which as discussed above is novel and non-obvious. However, in addition, Applicants submit that claims 18-21 also recite ranges of glycolide not taught or suggested by any of the cited references. Accordingly, Applicants respectfully request allowance of new claims 18-21.

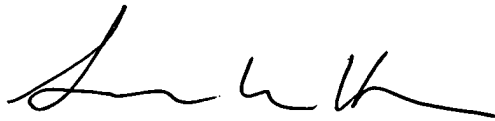
CONCLUSION

Applicants assert that the claims are in condition for immediate allowance and early notice to that effect is earnestly solicited. Should the Examiner deem that any further action by Applicants' undersigned representative is desirable and/or necessary, the Examiner is invited to telephone the undersigned at the number set forth below.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

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